

TSCA HEALTH & SAFETY STUDY COVER SHEET

TSCA CBI STATUS:

RECEIVED
G-PT 0110

08 JUL 28 AM 6:05

1.0 SUBMISSION TYPE

☐ 8(d) ☒ 8(e) ☐ Contains CBI
☒ Initial Submission ☐ FYI ☐ 4
☐ Follow-up submission
 Previous EPA Submission Number or Title if update or follow up:

☐ OTHER: Specify
☐ Final Report Submission
 Docket Number, if any:

☐ Continuation sheet attached

2.1 SUMMARY/ ABSTRACT ATTACHED

(may be required for 8(e): optional for §4, 8(d) & FYI)

☒ YES

☐ NO

2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID

7006-2150-0001-9158-5776
08-0093

2.3 FOR EPA USE ONLY

3.0 CHEMICAL / TEST SUBSTANCE IDENTITY

☐ Contains CBI

Reported Chemical Name (specify nomenclature if other than CAS name):

CAS # 118712-89-3 (2,3,5,6-tetrafluorophenyl)methyl (1R-trans)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate

☒ Single Ingredient
☐ Commercial / Tech Grade
☐ Mixture

Common Name: transfluthrin

4.0 REPORT / STUDY INFORMATION

☒ Study is GLP

Study Title: NAK 4455 Study for chronic toxicity and carcinogenicity in Wistar Rats

Study No: T8025696

Source of Data / Study Sponsor (if different than submitter)

Bayer CropScience LP

☐ Continuation sheet attached

5.0 STUDY / TSCATS INDEXING TERMS

(CHECK ONE)

HEALTH EFFECTS (HE): ☒

ENVIRONMENTAL EFFECTS (EE): ☐

ENVIRONMENTAL FATE (EF): ☐

6.0 SUBMITTER INFORMATION

J. Michael Wey

Head – Health, Safety, Environment Expertise Center
 Bayer CropScience - PO Box 12014, RTP, NC 27709

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Technical Contact:

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 Director, Regulatory Toxicology
 Bayer CropScience – PO Box 12014, RTP, NC 27709

Phone: 919-549-2973

☐ Continuation sheet attached.

7.0 ADDITIONAL / OPTIONAL STUDY COMMENTS ☐ Contains CBI

This compound is a pesticide not registered in the US.

☐ Continuation sheet attached

Submitter Signature:

J. Michael Wey

Date: July 17, 2008

Contains No CBI

CONTAINS NO CB



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8.0 CONTINUATION SHEET

Submitter Tracking Number / Internal ID

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08-0093

Continuation of 2.1

Reporting was based on the following results:

The compound was evaluated for chronic toxicity and carcinogenicity in groups of sixty male and female Wistar rats at concentrations of 0, 20, 200, and 2000 ppm for up to 25 months in their diet. Ten additional rats per dose group and sex were available for interim examinations after twelve months.

In the kidneys of rats treated for twelve months in the 200 and 2000 ppm groups a yellow-brown pigment was noted quite frequently. In addition males from 200 ppm exhibited increased nephropathy frequently, which points to an advanced ageing process.

Rats in the 2000 ppm dose group exhibited an increased incidence of urothelia hyperplasia. The slightly increased incidence of urinary bladder tumors in this group is considered due to the concentration and precipitation of test material in the urine, chronic irritation and regenerative hyperplasia. The test compound is not assessed as a primary carcinogen on this organ.

The concentration of 20 ppm is considered as the NOEL (No Observed Effect Level) for both males and females.

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